REMARKS

Claims 11-20 are currently pending in the instant application.

Applicants request reconsideration of the objections and rejections as stated in the Office Action dated September 8, 2004, based on the following remarks.

Claim Rejections - 35 U.S.C. § 102

In the Office Action, dated September 8, 2004, the Examiner maintained the rejection of Claims 11-13 and 15-17 under 35 U.S.C. § 102(b) as being anticipated by Franz *et al.* (U.S. 4,411,882). The Examiner asserted:

> ...the broadest reasonable interpretation of the limitation "plant substance" does not exclude Ergot alkaloids because it does not limit such substances to any specific plants. Plant substances as describe[ed] in page 6, para 0021 of the specification are any substance that may be derived from plants. Ergot Alkaloids fall within the scope of the limitation, because it is isolated from a *Clavicep purpurea* that grows on rye and wheat and thus is derived from a plant. Therefore, Ergot alkaloids are within the scope of such limitation.
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> Further, Examiner adds that the term fungus, as described by Webster's II, New Riverside University Dictionary, is describ[ed] as any of numerous plants of the division or subkingdom Thallophyta. See Webster II at p. 512. Since *Clavicep Purpurea* is a fungus within the meaning of Webster's II, it [] thus fall[s] within the kingdom of plant. Therefore, alkaloid ergots are viewed to be within the scope of the instant limitation of "plant substance."

Applicants respectfully assert that the Examiner is incorrect and request that the Examiner reconsider the rejection. First, Applicants note that the definition of "fungus" as recited in Webster II at p. 512 is ***outdated***. Fungi are no longer classified as part of the Plant Kingdom. Rather, fungi are classified as a separate kingdom as part of the "Five Kingdom Classification" created by Robert Whittaker. *See* Natural History – Phylogeny, (copy of webpage enclosed herewith and available at http://www.nearctica.com/nathist/phylog.htm, hereinafter "Natural History – Phylogeny"). As stated in Natural History – Phylogeny:

> The phylogeny of living organism has changed dramatically in the past few years. As a consequence you will find that different sites may give[] different, ***and sometimes conflicting, systematic arrangements for the same group of organisms.*** Nowhere is this more true than for the "lower organisms," i.e. those groups traditionally treated as bacteria, protozoans, algae and fungi. The traditional older arrangement divided [life] into two main group[s]; the Monera (bacteria and blue-green algae) and the Eucaryotes (protozoa, algae, plants, fungi, and animals). This older scheme was [supplanted] by the so-called "Five Kingdom Classification" created by Robert Whittaker. The "Five Kingdom Classification" divided all living organisms into five kingdoms:
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> - Kingdom Monera – Bacteria and blue-green algae
> - Kingdom Protista – Protozoa and some of the algae
> - ***Kingdom Plantae – Plants***
> - ***Kingdom Fungi – Fungi***
>   - Chytridiomycota (Chytrids)
>   - Zygomycota (Bread molds)
>   - Ascomycota (Sac and cup fungi, yeasts mildews)
>   - Basidiomycota (Club fungi, rusts and smuts)
>   - Fungi Imperfectae
>   - "Lichens"
> - Kingdom Animalia – Animals

See Natural History – Phylogeny at page 1. As indicated, *Claviceps purpurea* belongs to the fungal division "Ascomycota," which is not considered to be part of the Plant Kingdom. As such, *Claviceps purpurea* is not properly considered to be a "plant."

Further, one skilled in the art would not interpret "plant substance" to include *Claviceps purpurea*. The Plant Kingdom and Fungal Kingdom are classified separately based on distinguishing characteristics. First, all members of the Plant Kingdom are photosynthetic autotrophs, meaning that they contain chlorophyll and use light a source of

energy to synthesize carbohydrates, lipids, proteins, and other organic molecules. Fungi, in contrast, are heterotrophs, meaning that they have to absorb their nutrients from the surrounding medium by secreting food acids and hydrolytic enzymes. As such, fungi are not plants, and in fact, fungi like *Claviceps purpurea* are pathogens of plants that secrete enzymes to degrade and absorb nutrients from plants such as corn, wheat, and rye. Fungi, like *Claviceps purpurea*, decompose complex molecules in plants to simpler compounds that the fungi can absorb and assimilate. Similarly, animals such as birds, mice, and humans are heterotrophs in that animals ingest corn, wheat, and rye to digest complex molecules and obtain nutrients from simpler compounds. One skilled in the art would not consider *Claviceps purpurea* to be a "plant substance" (*i.e.*, "a substance derived from a plant") for the same reason that one skilled in the art would not consider birds, mice, and humans to be "plant substances" (*i.e.*, "substances derived from plants"). Heterotrophs ***degrade "plant substances"*** into simpler compounds (*e.g.*, by secretion, ingestion, *etc.*) and assimilate the simpler compounds. Therefore, one skilled in the art would not consider heterotrophs, such as *Claviceps purpurea*, to be "derived from a plant substance."

With regard to the limitation "neutral core," the Examiner argues that "'neutral core' should be given its broadest reasonable interpretation consistent with the specification." As such, the Examiner argues that "neutral" should be viewed to mean "free of charge" and that "core" should be viewed to mean the innermost layer. Finding as such, the Examiner contends that Franz *et al.* meet all the elements of the instant claims.

Applicants respectfully traverse the rejection and ask the Examiner to reconsider the rejection for the following reasons. First, Applicants agree that the limitation "neutral core" should be given its broadest reasonable interpretation consistent with the specification. However, Applicants emphasize that the broadest interpretation must be ***reasonable*** and ***consistent with the specification***.

The limitation "neutral" may be interpreted to be synonymous with "inert." *See* dictionary.com definitions of "neutral" and "inert," copy of webpages enclosed herewith and available at http://dictionary.reference.com/search?q=neutral (hereinafter "neutral definition") and http://dictionary.reference.com/search?q=inert (hereinafter "inert

definition"), respectively. On page six (6) of the "neutral definition" from Webster's Revised Unabridged Dictionary © 1996, 1998 *MICRA, Inc.*, "neutral" is defined as "3: having only a limited ability to react chemically, ***not active; 'inert matter'***; 'an indifferent chemical in a reaction' [***syn: inert***, indifferent]." *See* "neutral definition" at page 6 of 7 (emphasis added).

Similarly, on page three (3) of the "inert definition" from Webster's Revised Unabridged Dictionary © 1996, 1998 *MICRA, Inc.*, "inert" is defined as "having only a limited ability to react chemically; ***not active***; 'inert matter'; 'an indifferent chemical in a reaction' [***syn:*** indifferent, ***neutral***]." *See* "inert definition" at page 3 of 4 (emphasis added). As such, "neutral" is reasonably interpreted to mean "inert," especially in a chemical context. Applicants note that the instant application relates to pharmaceutical preparations and contend that Applicants' proposed interpretation of "neutral" (*i.e.*, "inert") is ***more reasonable*** and ***consistent with the specification*** than Examiner's proposed interpretation (*i.e.*, "free of charge").

Further, those skilled in the art have interpreted "neutral" to mean "inert." Applicants have enclosed herewith product information sheets for NPpharm Suglets® (hereinafter "NPpharm Suglets®") and IPSsrl Pharmaceutical Sugar Spheres (hereinafter "IPSsrl Sugar Spheres"). As indicated by NPpharm, Suglets® are "Sphere de Sucre – ***Neutral Pellets*** – Sugar Spheres – ***Neutral Core***" that "Meet all the specifications of the USP/NF, Ph. Eur., JP." NPpharm also states that "[s]ugar spheres are ***inert pellets*** composed [of] sucrose and maize starch...Suglets are ***drug-free cores*** which are coated by a suspension or a solution of ***Active ingredients*** (with a binder)." *See* NPpharm Suglets® (emphasis added). As indicated by IPSsrl, "Sugar Spheres (***Neutral pellets***) are ***inert microgranules*** based on sucrose and corn starch." *See* IPSsrl, Sugar Spheres (emphasis added). As such, those skilled in the art use "neutral pellets" and/or "neutral cores" synonymously with "inert pellets" and/or "inert microgranules."

Therefore, viewing the specification and interpreting "neutral" in the context of pharmaceutical preparations, one skilled in the art would interpret "neutral core" to mean "inert core." Franz *et al.* do not teach or suggest "neutral cores" as that term is properly interpreted in view of the specification and in the proper context of pharmaceutical

preparations (*i.e.*, as "inert cores"). As such, Applicants respectfully contend that Franz *et al.* do not anticipate the instant claims and ask the Examiner to withdraw the rejection.

Claim Rejections - 35 U.S.C. § 103

In the Office Action, the Examiner also maintained the rejection of Claims 11-20 under 35 U.S.C. § 103 as being unpatentable over Franz *et al.*. Applicant respectfully traverse the rejection. As noted above, Franz *et al.* do not disclose "a layer containing ***a plant substance***" as recited in the pending claims. Neither do Franz *et al.* disclose coating a "***neutral core***" as recited in the pending claims. Therefore, Franz *et al.* do not disclose all the limitations of the pending claims.

Further, Franz *et al.* do not suggest the limitations of the present claims. The problem intended to be solved by Franz *et al.* is the preparation of a galenic composition of ergot alkaloids, with prolonged effect, and with an improved bioavailability (col. 1, lines 7-10). Franz *et al.* attempt to solve this problem by applying an ***enteric coating*** onto an ***active core*** to prepare a prolonged release formulation (col. 1, lines 28-35). In contrast, the present invention is not a prolonged release formulation. Rather, it relates to a process for preparing a reproducible, homogenous and stable formulation, allowing a high dosage of plant extract by coating a ***neutral core*** with a layer containing a ***plant substance***. As such, one skilled in the art, in view of Franz *et al.*, would not be motivated to perform the processes recited in the pending claims. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 103 over Franz *et al.*

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date 11/8/04

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